

Tolerance Results and Immune Mechanisms in Cow's Milk and/or Hen's Egg Allergic Children Following Natural Evolution or Oral Immunotherapy

NCT07419243

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Fundación de Investigación Biomédica - Hospital Universitario de La Princesa
Enrollment	68 participants

Key Eligibility Criteria

Inclusion (10)

- NAT-cohort:
- Cow's Milk and/or Hen's Egg allergic patients 4 to 10 years old
- sIgE levels to milk OR egg extracts between 0.35 to 35kUA/L
- Positive entry Open food challenge with milk/egg with oFASS5 classification e2 with a maximum cumulative dose of up to 4193.7 mg of milk protein or 3110.8 mg of egg white protein
- Having a mild to moderate food allergy severity per the Definition of Food Allergy Severity (DEFASE) score (<13 points)
- ... and 5 more (see full listing online)

Exclusion (25)

- NAT-cohort:
- Positive reaction in the entry open oral food challenge with a baseline Eliciting Dose (ED) 20 below the target ED20 for food. For milk, 23.1 mg (35.7 mg cumulative) of protein, or for egg, 19.5 mg (29.4 mg cumulative) of protein.
- Patient desire or medical indication to initiate OIT at any time within 29 months of study entry.
- No allergic reaction greater than oFASS5 grade 1 in the baseline challenge for the maximum cumulative programmed doses of 4193.7 mg of milk protein, or 3110.8 mg of egg white protein.
- Immunological diseases, immunomodulatory/blocking therapies.
- ... and 20 more (see full listing online)

Locations (1 total)

Hospital Infantil Universitario Niño Jesús. Avenida de Menéndez Pelayo, número 65, Madrid, Madrid, Spain